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A comparative study of postoperative analgesia and safety of intravenous nalbuphine versus intravenous tramadol in patients undergoing lower abdominal surgeries

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ABSTRACT

Introduction: Providing excellent pain relief is one of the primary priorities in postoperative care. Nalbuphine is an opioid analgesic that works as both an agonist and an antagonist and has a superior safety profile and fewer adverse effects than other opioids. Tramadol acts on opioid receptors and inhibits neuronal uptake of norepinephrine and serotonin. *Aims and objectives*: To compare intravenous inj. Nalbuphine (0.1mg/kg) with intravenous inj. Tramadol (1mg/kg) in terms of duration of post-operative analgesia, sedation and any adverse effects. *Methodology*: Two equal groups of 30 participants each were selected randomly from 60 female patient posted for lower abdominal gynecological surgeries - Group N and Group T. The Group N candidates were administered with inj nalbuphine 0.1mg/kg IV and those in the group T were administered with inj tramadol 1mg/kg IV when they complained of pain post operatively, VAS >3 and rescue dose was repeated whenever the VAS score was >3. We compared the postoperative analgesia in both the groups along with sedation and adverse effects. *Results:* Group N showed lower VAS scores and better sedation scores than Group T. The duration of analgesia was longer in group N when compared to group T. Group N patients had comparatively less side effects than Group T patients. *Conclusion*: Nalbuphine at the dose of 0.1mg/kg not only had a better analgesic effect than tramadol 1 mg/kg, but also a more sedative effect with fewer adverse effects when given intravenously.

Keywords: Nalbuphine, Tramadol, Postoperative analgesia, lower abdominal surgeries

1. INTRODUCTION

One of the key goals of postoperative treatment is to offer excellent pain reduction for surgical patients. Medicines that give excellent pain relief with very little side effects are desired. To manage pain during the postoperative phase, a variety of drugs are available that can be taken via various routes (Garimella & Cellini, 2013). Opioid analgesics are frequently employed in alleviating moderate-to-severe pain and therapy based on opioid is the treatment of choice for postoperative pain (Inturrisi, 2002). These medications have been used in both adults and children who have undergone surgery. Sedation, respiratory depression, constipation, nausea, vomiting, and urine retention are all side effects of opioid analgesics. Although the sedative impact of these drugs may be advantageous in individuals undergoing surgery, some side effects are unwelcome throughout the postoperative phase (Gong et al., 2018). Various drugs like tramadol, ketorolac, dexmedetomidine, ketamine and nalbuphine have all been used to extend postoperative analgesia.

The synthetic opioid, Nalbuphine is an agonist-antagonist pain killer that is principally a kappa (κ) agonist and a partial mu (μ) antagonist. As an outcome of its antagonist and agonist properties, it has a superior safety profile with a very few adverse effects than other opioids (Bakri et al., 2016). Nalbuphine's analgesic and hypnotic actions are mediated through the kappa (κ) opioid receptor that might help in lessening the adverse effects that are related to mu (μ) opioid receptor. Its benefits in pain treatment have been documented in numerous researches (Shin et al., 2001).

Tramadol is a commonly used analgesic medication which is centrally acting and is frequently used to relieve post-surgical pain. When compared to morphine, it has around 10% of the potency when given parenterally (Grond & Sablotzki, 2004). Tramadol has dual mechanisms of action via acting on opioid receptors it decreases norepinephrine absorption and also serotonin absorption by the neurons. It exhibits a lower risk of respiratory depression when compared with other opioids because of its non-opioid activity. However, tramadol usage in postoperative patients has been linked to an increased risk of nausea and emesis (Solanki et al., 2015).

Nalbuphine has been recommended to be a superior analgesic than tramadol in postoperative pain management since it causes less nausea and vomiting (Jitendra Kumar et al., 2017).

Aims and objectives

Aim

To compare the effectiveness of Nalbuphine and Tramadol as post-operative analgesics

Objectives

Primary objective

To examine the duration of post-operative analgesia with Nalbuphine and Tramadol

Secondary objectives

To compare Nalbuphine and Tramadol in terms of sedation

To determine the occurrence of any side effects with Nalbuphine and Tramadol

Sample size calculation

Sample size calculation was done using Open Epi, version 3 Assuming the duration of analgesic action as 6.05 hours and standard deviation of 3.14 hours with reference to a previous study (Shetty and Devdas, 2018), keeping the power at 80% and confidence interval at 95% (alpha error at 0.05) To detect a minimum of 50% difference in analgesia duration among the two groups, a sample of 28 patients would be necessary. We include 30 participants in each group to compensate for the possible dropouts.

2. MATERIALS AND METHODS

The research was carried out in Department of Anesthesiology of a tertiary care center after obtaining clearance from Institutional Ethical Committee (IEC number: IEC/Sept-2019/8367). Sixty female patients posted for elective lower abdominal gynecological surgeries were selected after considering inclusion and exclusion criteria. They were categorized into two equal groups containing 30 patients each after random selection – Groups N and T. Group N received Inj. Nalbuphine 0.1mg/kg IV and Group T received Inj. Tramadol 1mg/kg IV.

Study design

This is a prospective randomized comparative observational study

Study period

2 years (October 2019 – October 2021)

Inclusion criteria

Patients of ASA grade I - II
Age group of 30-70 years
Patients undergoing elective lower abdominal gynecological surgeries under S.A.B
Patient consent

Exclusion criteria

Patients allergic to the drugs
Patients on Oral anticoagulant therapy, Neuroleptic agent, Mono amino oxidase inhibitor, Patients with History of epilepsy, increased intracranial tension, History of motion sickness, Opioid using history since last 1 month, Patients who refused to be a part of the study, Intraoperative sedation or analgesic given IV or IM.

All the patients had undergone a pre-anaesthetic evaluation a day before surgery. A detailed history was elicited and a thorough general and systemic evaluation was performed to rule out any congenital diseases, cardiovascular, respiratory, and neurological or any associated problems. An airway and spine examination was also done. Documentation of baseline blood pressure (both sBP and Dbp), heart rate (HR), respiratory rate (RR), temperature and weight were done. Inform all the patients regarding the procedures of anaesthesia and surgery. Written informed consent was taken on the day before surgery. All patients were explained about the use of 'Visual analogue pain scale' (VAS) and descriptor words of pain in a language familiar to the patient. The pain assessment was carried out using visual analogue scale which is described below.

The VAS is a ten-centimeter line with two end points: "no pain" and "pain as bad as it gets." On this line, the patient is requested to make a mark reflecting the intensity of the pain (figure 1). The VAS score is calculated by measuring the distance in centimeters between the left extreme of the scale that indicates "no pain" and the point indicated by the patient (Rani et al., 2014).

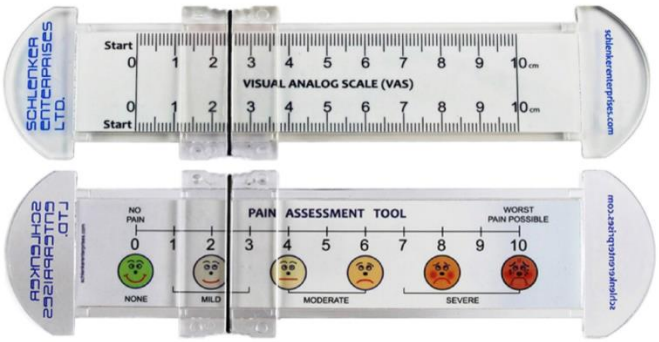


Figure 1 Visual Analogue Scale

Assessment of sedation was carried out according to Modified Ramsay sedation scale (table 1) (Arunkumar et al., 2015). In all of the patients, the surgical procedure was done under spinal anaesthesia. The drug used was 3.5cc of 0.5% heavy bupivacaine. No other analgesics or sedatives drug were given intraoperatively. Vitals were again monitored and documented in post anaesthesia care unit. The candidates in the group N received inj nalbuphine 0.1mg/kg IV when they complained of pain post operatively, VAS >3 and rescue dose was repeated whenever VAS score was >3. The candidates in the group T received inj tramadol 1mg/kg IV slowly when they complained of pain post operatively, VAS >3 and rescue dose was repeated whenever VAS score was >3. The 0^{th} minute is the time when the study drug is administered and the time period between 0^{th} minute to the time when patient again complained of pain (VAS >3) is taken as duration of analgesia. Vitals (PR, BP, RR, SPO2), pain and sedation assessment done at 0min, 5min,10 min, 30min, 1hr, 2hrs, 3hrs etc to 24hrs. Pain and sedation assessments were not done during the night time as all

patients were on their natural sleep. If the drug does not relieve the pain, then supplementation with Inj Diclofenac or Neomol infusion was considered. Adverse effects and time of its occurrence were noted as follows (table 2).

Table 1 Modified Ramsay sedation scale

DEFINITION	SCORE
Anxious, agitated, restless	1
Cooperative, oriented, tranquil	2
Responds to commands only	3
Brisk response to light glabellar tap or loud noise	4
Sluggish response to light glabellar tap or loud noise	5
No response	6

Table 2 Adverse effects and time at which noted

Adverse effects	Time at which noted
Headache	
Nausea	
Vomiting	
Weakness	
Sweating	
Dizziness	
Dyspepsia	
Any other	

Statistical analysis

Data were entered in Microsoft excel software and analyzed using STATA software version 12(manufactured by Stata Corp LP, College Station, Texas). In either of the groups, continuous variables such as Age, SBP, DBP, HR, RR etc. are expressed as mean and standard deviation. Categorical independent variables were summarized as proportions between both groups. Continuous variables were compared among both groups using independent t-test, while categorical variables were compared using Chi-square or Fisher's exact test depending on the distribution. A p value of less than 0.05 was considered significant in all statistical interpretations.

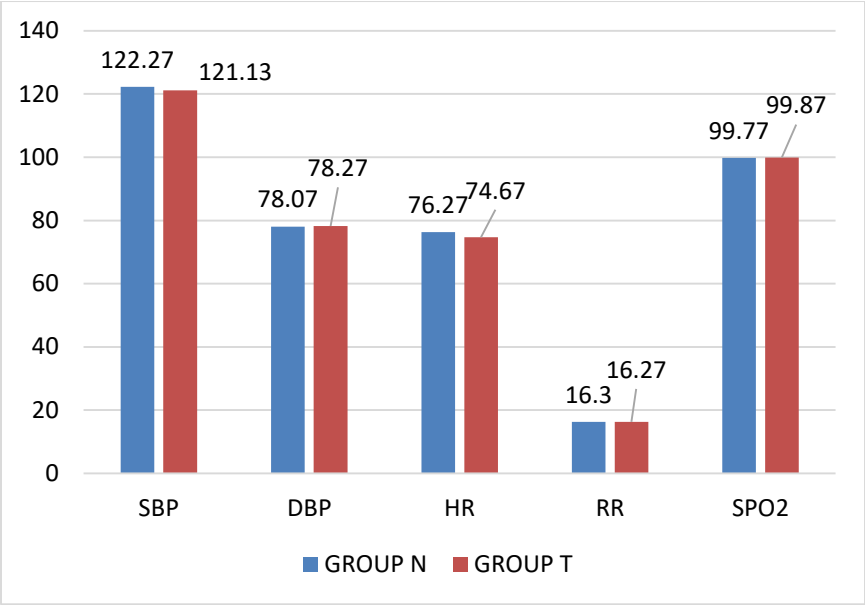
3. RESULTS

In group N, the mean for the age of the participants were 45.47$\pm$ 8.415 years whereas it was 44.80 $\pm$ 5.821among the group T (table 3). The age was comparable among both groups as the p value was not significant (p>0.05).

Table 3 Age distribution of the study population

	GROUP	n	Mean	Std. Deviation	P value
AGE	N	30	45.47	8.415	0.722
	T	30	44.80	5.821	

The present study assessed the baseline parameters such as systolic as well as diastolic BP, heart rates, respiratory rate and SPO2. In groups, all pre-operative or baseline parameters were comparable. There wasn't any significant statistical association (p>0.05) between the baseline parameters when it was compared using independent t test (graph 1). The study has higher weight among the Group T (57.8$\pm$7.78) compared to Group N (55.3$\pm$6.85) which was statistically insignificant (p=0.185) (table 4).

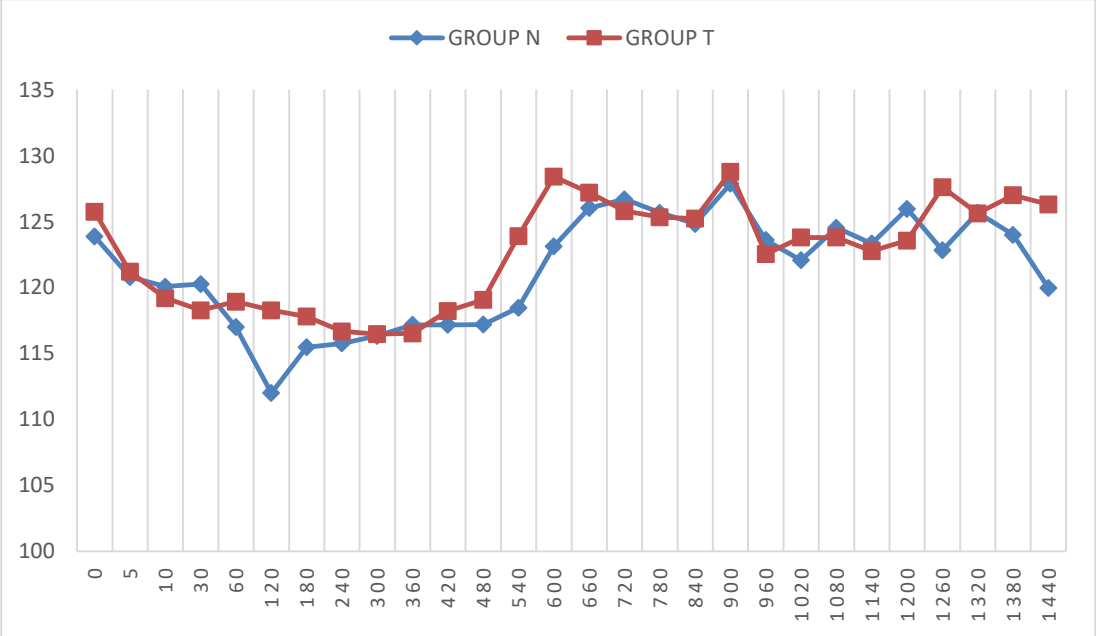


Graph 1 Baseline vital parameters

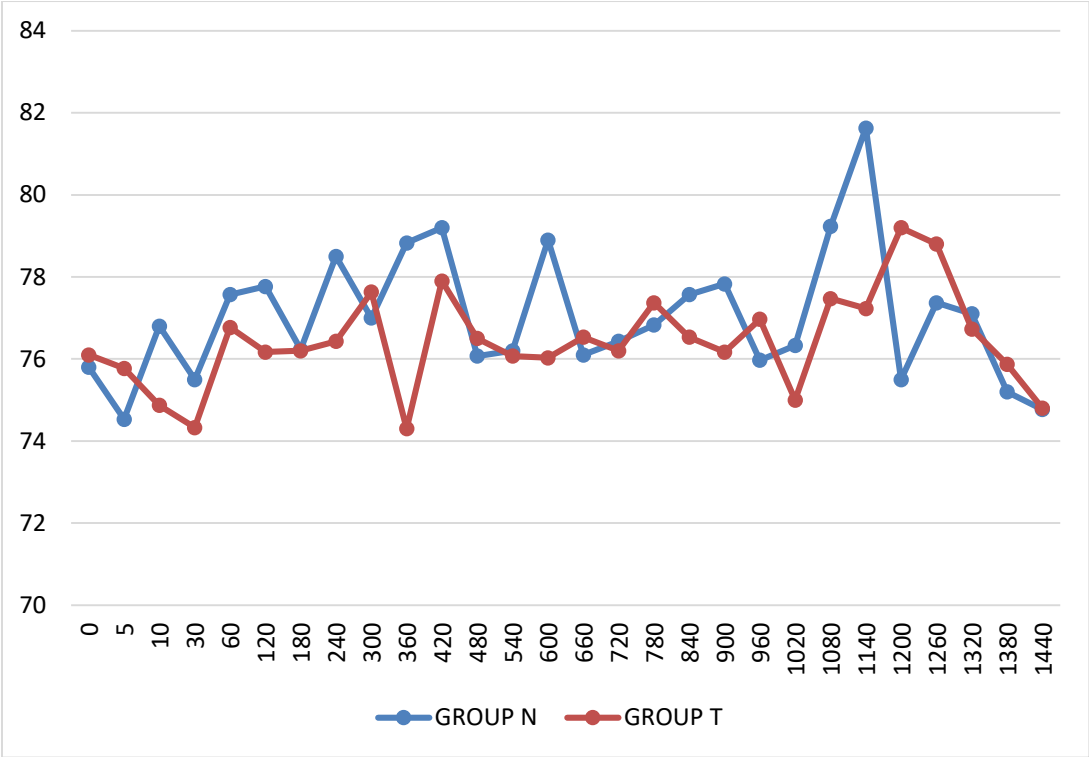
Table 4 Comparison of weight among the study population

	GROUP	N	Mean	Std. Deviation	P Value
WEIGHT	N	30	55.3	6.85	0.185
	T	30	57.8	7.78	

Systolic BP was comparable during all intervals of time. The change in systolic BP value didn't have any statistical significance ($p>0.05$) when it underwent independent t test (graph 2). Diastolic BP was comparable during all intervals of time. The change in diastolic blood pressure value didn't have any statistical significance ($p>0.05$) when it underwent independent t test (graph 3).

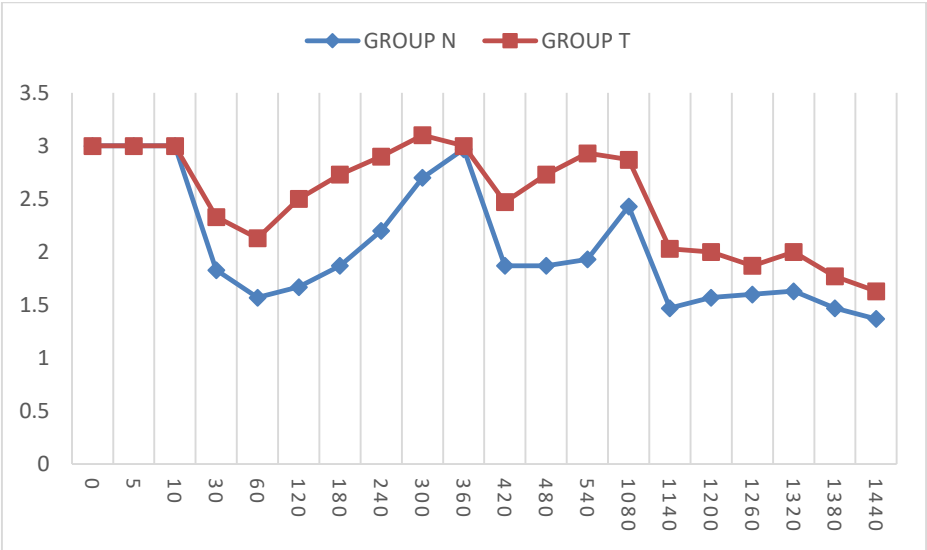


Graph 2 Line diagram showing comparison of systolic BP among study population at different intervals of time.

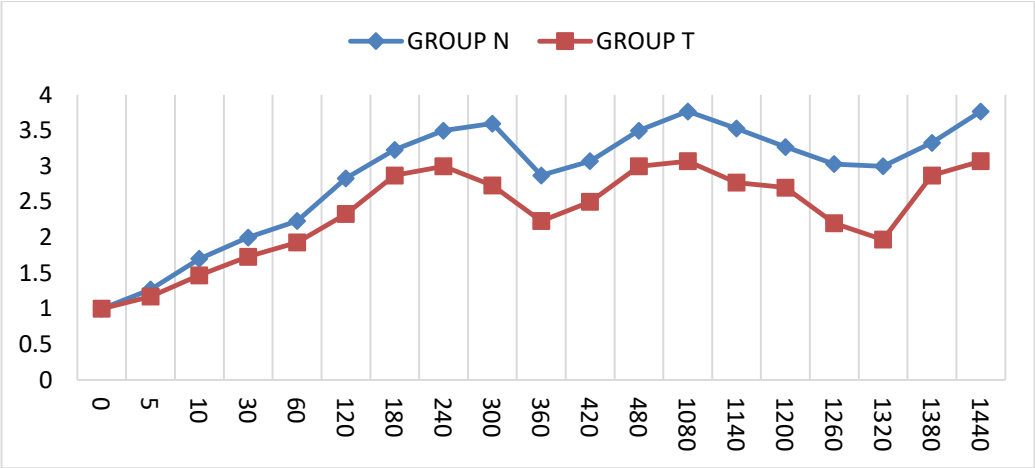


Graph 3 Line diagram showing comparison of diastolic BP among study population at different intervals of time.

The current study had respiratory rate (RR), heart rate (HR) and SpO2 (oxygen saturation) being comparable since there isn't any statistically significant difference among both the drugs at any interval in both groups. No signs of fluctuation in any of these parameters beyond physiological range were noted. The mean VAS score for Group N was lower than Group T through all intervals of time in this study .The difference in VAS scores were statistically significant among almost all intervals of time except for 360 and 1260 minutes (graph 4).



Graph 4 Line diagram showing comparison of VAS scores



Graph 5 Comparison of sedation scores among the study population at different intervals of time.

The sedation scores of group N were consistently greater than those of group T in this study (graph 5). This better sedation scores in group N had a statistically significant association ($p<0.05$). This study found that duration of action among Group N in comparison with Group T is more (5.27±0.640 hours vs 3.43 ±0.728hours). This result had got a significant statistical association ($p<0.05$) (table 5).

Table 5 Comparing the duration of analgesic action among the study population

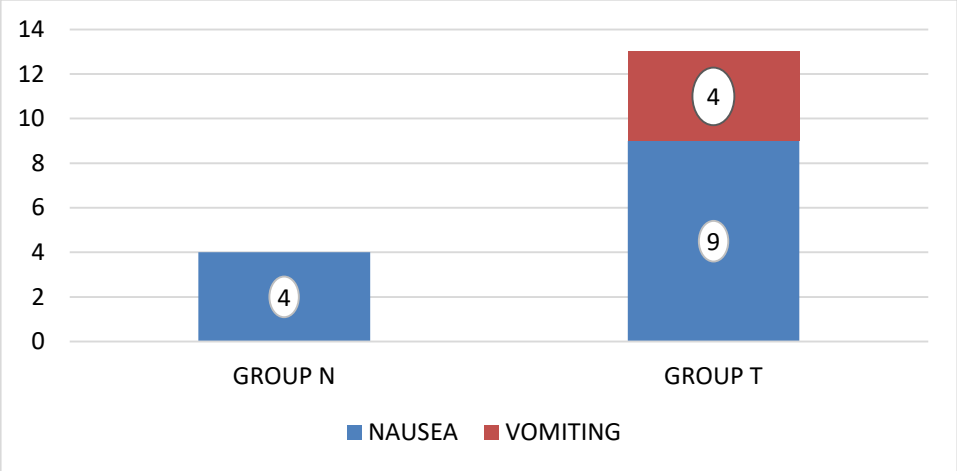
	GROUP	n	Mean	Std. Deviation	P value
DOA IN HOURS	N	30	5.27	0.640	<0.001
	T	30	3.43	0.728	

The current study found that only 4 among Group N had adverse effects compared to 13 among the Group T. 13.34% of the patient in group N had nausea where as 30.0% of the participants in group T had nausea. That is, out of 13 who had nausea 69.2% (n=9) belonged to Group T. 13.34% of participants in group T had vomiting whereas none of the participants in group N had vomiting. This result had shown a significant statistical association ($p<0.05$). No adverse effects other than these were noticed. (table 6 and graph 6).

Table 6 Comparing the adverse effects among the study population

		GROUP		TOTAL	P value
		N	T		
ADVERSE EFFECTS	NAUSEA	4	9	13	0.020
		13.34%	30.0%		
	VOMITING	0	4	4	
		0.0%	13.34%		
	HEADACHE	0	0	0	
		0.0%	0.0%		
	DIZZINESS	0	0	0	
		0.0%	0.0%		
	WEAKNESS	0	0	0	
		0.0%	0.0%		
	SWEATING	0	0	0	
		0.0%	0.0%		
	DYSPEPSIA/ FEELING OF BLOATING	0	0	0	
		0.0%	0.0%		
	NIL	26	17	43	

		86.66%	56.66%		
Total		30	30	60	
		100.0%	100.0%		



Graph 6 Side effects comparison among both groups

4. DISCUSSION

Despite the fact that pain is an unavoidable part of the postoperative experience, poor pain management is all too common. Many recent researches have corroborated this. Untreated postoperative pain can result in physiological and psychological changes in patients, increasing morbidity and mortality. We could find out the comparable effectiveness and safety profile of nalbuphine as a pain killer against the commonly used medication tramadol, both delivered intravenously, in our prospective randomized comparative observational study. The majority of opioid agonists are successful in the treating acute pain. Their use, however, is not necessarily without drawbacks. Their widespread usage for acute post-operative pain treatment is limited due to nausea, vomiting, pruritis, excessive sedation and respiratory depression. In addition, the availability of opioid agonists has recently been constrained.

Tramadol is a mild opioid μ receptor agonist that is often used to alleviate post-operative pain at the dosage of 1-2 mg/kg. However, the analgesic effect in post-surgical patients is not always proven to be satisfactory at the prescribed dosage. Pang et al., (1999) demonstrated that analgesia with tramadol PCA can be quite effective after major orthopaedic surgery if sufficiently high loading doses are administered and patient demand is met. They noticed an increase in nausea and emesis with decrease in patient satisfaction, in patients who received such large doses. Beaver & Feisein (1978) showed that nalbuphine is nearly as efficacious as morphine. We utilized 0.1 mg per kg body weight of nalbuphine and 1 mg per kg body weight of tramadol, which are similar to the levels used by other researchers.

We included patients who received spinal anaesthesia and no other regional anaesthesia procedures in our current investigation. This is significant in terms of the effects of analgesia seen in the postoperative phase. If such a situation had occurred, it may have impacted our study by causing universally lower pain scores reported by the patient, resulting in an artificially inflated efficacy of study drugs. Aside from that, we've only used analgesics after the effects of spinal anaesthetic have worn off and patients have a VAS score of 3 for pain. All of our patients had a VAS score of 3 when the analgesic injection was administered. The time it took for the both groups to acquire VAS score of 3 differed. This can be due to a lot of factors impacting spinal anaesthesia and also the length of the surgical operation.

However, because the analgesia was delivered and parameter collection began only at a certain point (VAS pain score of 3) that is after the anaesthetic effect has faded off, this time-lag element should not alter the study's outcome. Because the plasma concentration attained with intrathecal bupivacaine injection is negligible and no other drug is administered intra operatively, the chances of any drug interactions or impacts with the study drug are slim. Here in the current study, self-reports of pain were utilized to measure pain. These self-report are crucial in determining therapy effectiveness. Valid self-reports of pain have indeed been proven to be helpful in the treating those who are in pain, whether it's acute or chronic, by clinical researchers.

Group N provides much superior pain relief than group T during the course of the research. Except for the 360th and 1260th minutes, the difference in VAS scores was statistically significant among almost all time intervals. The statistical discrepancy found could be attributable to differences in peak actions of two different medications. All patients received analgesic drugs whenever

their VAS score was 3. The pain assessment revealed low VAS scores at 30 minute after each dose compared to other various time intervals owing to higher plasma levels of respective drugs after intravenous administration. There is a superior analgesic efficacy shown by intravenous Nalbuphine than tramadol at each interval with respect to VAS score during the research. Statistically significant variation in analgesic activities were seen in our investigation, apart from the assessments at the 360th and 1260th minutes, showing that Nalbuphine had higher analgesic efficacy in our patients. Pain evaluation was not possible in all patients from the 540th minute to the 1080th minute, as this was the patients' sleeping hour and hence could not be examined. We assumed that the patients were pain-free; otherwise, an additional analgesic would be required. During the study's sleep hours, no subject required additional analgesics.

Siddiqui and Chohan (2007) compared the results of intravenous tramadol 1.5mg/kg with intravenous nalbuphine 0.1mg/kg for minor surgeries utilizing TIVA (total intravenous anaesthesia) with a propofol infusion. They concluded that patients who received nalbuphine had a stable haemodynamics, better recovery and improved pain control while comparing to tramadol group patients. Hence outcome of this study correlates with our findings. Shetty and Devdas (2018) studied the effectiveness of intravenous nalbuphine 0.1mg/kg versus tramadol 1mg/kg for postoperative analgesia in adult patients who underwent lower abdominal surgeries under subarachnoid block. They concluded that Nalbuphine had marginally superior analgesic action than tramadol. Their result coincides with the findings of our study. Solanki et al., (2015) when compared the post-operative effectiveness of intravenous Nalbuphine 0.15 m g/kg and intravenous Tramadol 2 mg/kg for analgesia in patients scheduled for orthopaedic surgeries under regional or general anesthesia or combination of both techniques observed that Nalbuphine provides superior pain relief to tramadol.

Jitendra Kumar et al., (2017) after comparing intravenous Nalbuphine at 0.25mg/kg with intravenous Tramadol at 2mg/kg in patients scheduled for elective short surgical procedures done by TIVA came to the conclusion that Nalbuphine is a better analgesic for treating postoperative pain in brief surgical operations than Tramadol. The result coincides with our study findings. Sedation evaluation was not done in all patients from the 540th minute to the 1080th minute, as the patients were sleeping during this time period, and hence could not be examined. The analysis shows that the sedation scores of group N were consistently greater than those of group T. This better sedation scores in group N had a statistically significant association ($p<0.05$).

Moyao Garcia et al., (2009) after comparing the safety and effectiveness of intravenous nalbuphine (100 μg/kg followed by an infusion of 0.2 μg/kg/min for 72 hrs) and intravenous tramadol (1000 μg /kg followed by an infusion of 2.0 μg/kg/min for 72 hrs) as postoperative analgesic in children found that sedation was more with Nalbuphine. Here the study population is in pediatric age group whereas age of our study population is between 30-70 years. Shetty and Devdas (2018) after comparing the efficacy of intravenous nalbuphine 0.1mg/kg versus tramadol 1mg/kg for postoperative pain management in adult patients who underwent lower abdominal surgeries under subarachnoid block observed that Nalbuphine had a stronger sedative effect and a similar effect on respiratory depression, which is advantageous during the stressful postoperative period. This observation correlates our study.

Kamath et al., (2013) also concluded that Nalbuphine provides decent sedation after their comparative study between intravenous. Nalbuphine 0.2mg/kg and intravenous tramadol 1mg/kg is an analgesic in the post-operative period. This supports our study findings. As the postoperative period is stressful, nalbuphine's mild to moderate sedative effect may be beneficial to the patient. Furthermore, the sedation it caused was never high enough to cause concern about the patient's respiratory depression. Such sedation decreases surgery-related anxiety and provides much-needed consolation to the patient postoperatively and thus should be considered a nalbuphine advantage.

The 0^{th} minute was defined as the time when the research drug was administered and the time period between 0^{th} minute to the time when patient again complained of pain (VAS >3) is taken as duration of analgesia. This study found that Group N had comparatively more duration of action than group T (5.27 ± 0.640 hour's vs 3.43 ± 0.728hours). This result had got a significant statistical association ($p<0.05$). Agrawal et al., (2019) compared analgesic effectiveness as well as adverse effects of Tramadol (50mg) vs Nalbuphine (5mg) as an additive with 0.125% Bupivacaine plain epidurally. They observed that Nalbuphine 5mg as an addition with 0.125 percent Bupivacaine was effective and when compared to Tramadol 50mg as it provided a faster onset as well as longer sensory blockade duration thus better pain relief with a lower VAS score. Their finding coincides with the findings of our study, even though both Nalbuphine and tramadol are given epidurally.

The current study had respiratory rate (RR), heart rate (HR) and SpO2 (oxygen saturation) being comparable since there isn't any statistically significant variation between two drugs at any interval. No signs of fluctuation in any of these parameters beyond physiological range were noted. Inadequate analgesia is associated with fluctuating cardiovascular reactions such as tachycardia. This response can be avoided with by using an efficient analgesic. Analgesic drugs' sedative properties may help mitigate this impact. Both tramadol and nalbuphine are noted to have no direct cardiovascular effects. We were fortunate in not finding any substantial or clinically significant changes in haemodynamic within either group, or any differences in values between the two. If

such effects had been documented, it would have been challenging to reconcile the relative contributions of such pharmaceutical actions and the pain itself to the data.

Shetty and Devdas (2018) after comparing Nalbuphine and Tramadol concluded that both the drugs provide comparable haemodynamic stability. This finding coincides with our study. Siddiqui and Chohan (2007) and Solanki et al., (2015) reported better haemodynamic stability in Nalbuphine in comparison with Tramadol. The current study found that only 4 among Group N had adverse effects compared to 13 among the Group T. 13.34% of the candidates in group N had nausea where as 30.0% of the candidates in group T had nausea. That is, out of 13 who had nausea 69.2% (n=9) belonged to Group T. 13.34% of candidates in group T had vomiting whereas none of the participants in group N had vomiting. This result had shown a significant statistical association ($p<0.05$). No adverse effects other than these were noticed.

Nausea and emesis caused by opioids are due to stimulation of the chemoreceptor trigger zone in the area postrema of the medulla, potentially through delta receptors. Early postoperative nausea and vomiting (PONV) is a well-known complication that may be triggered by a number of reasons, including pain discomfort. This unfavorable effect could have been caused by surgical reasons of nausea and emesis, surgery kind and length, and other unknown reasons. Higher incidence of nausea and emesis reported with tramadol group patients in the most of the previous comparative studies with Nalbuphine and Tramadol. Nalbuphine was found to have a significantly decreased incidence of nausea and emesis (Moyao Garcia et al., 2009; Kamath et al., 2013; Solanki et al., 2015; Jitendra Kumar et al., 2017; Shetty & Devdas, 2018).

Ntritsou et al., (2013) after comparing the efficacy of postoperative analgesia and adverse effects after administration of nalbuphine, morphine, and tramadol intravenously in conjunction with IV ketamine reported that PONV was much more common in the Nalbuphine and Morphine groups. It is contradictory to our findings. But it is essential here to point out that Nalbuphine and Tramadol were given along with Ketamine IV, which may alter the findings due to drug-drug interaction. The likelihood of interactions with other analgesic medicines administered intra-operatively and prior to the commencement of the study parameters evaluation was carefully evaluated. Long-acting analgesics (for eg: Diclofenac) may have a considerable impact on early post-operative pain, either on their own or in combination with the study medicines. However, in either of the groups, we employed just spinal anaesthesia as the preferred approach, with no extra analgesics, removing the possibility of drug interactions. None of the participants in the study required any other extra pain killer supplementation as they were getting relief with both the study drugs

5. CONCLUSION

Nalbuphine at the dose of 0.1mg/kg had a better analgesic effect than tramadol 1 mg/kg, as well as a more sedative effect with lesser side effects, which is beneficial in the postoperative period, so Nalbuphine at the dose of 0.1mg/kg IV is recommended for use in patients undergoing lower abdominal surgeries under subarachnoid block as post-operative analgesic.

Advantages of our study

Our study design had the obvious advantage of using solely spinal anaesthetic for all patients, with no sedatives or analgesics administered intraoperatively. As a result, the chances of a drug interaction and its impact on the study drug are nil. All the participants in our study were of same sex (female), which helped to remove sex differences in pain sensitivity and analgesic response. All the participants had a hysterectomy, so the tissue trauma associated to the extent of operation was equivalent.

Limitations of our study

We have not analyzed pain levels during natural sleep hours during our 24-hour analysis. This could have an impact on our pain scores. Psychological component and differences in pain threshold among patients may have an impact on our findings. We have included only patients from the age group of 30 to 70 years and those who come under ASA I and II. The small sample size in each group may have lowered the statistical analysis of our study.

Recommendations

Utilizing Nalbuphine as post-operative analgesic in patients of ASA grade III and IV; Utilizing Nalbuphine as post-operative analgesic in paediatric age groups under supervision and continuous monitoring; Utilizing Nalbuphine as post-operative analgesic with reduced and increased doses; Compare Nalbuphine with other opioid analgesics

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Author contributions

Dr.Shiras P: Primary and corresponding author, Data collection and analysis, compilation, case management in the OT
Dr.Sanjot Ninave: Final review of the article to be published, Head of the team supervising the case, case management in the OT
Dr.Aruna Chandak: Data analysis and compilation, Conception of or Design of the article.
Dr.Amol Bele: Data analysis and interpretation
Dr.Nikhil Bhalerao: Data analysis and interpretation
Dr. Shuguftha Sherin: Data analysis and interpretation

Informed consent

Written & Oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

Ethical approval

The study was approved by the Medical Ethics Committee of Datta Meghe Institute of Medical Science University, Sawangi (M), Wardha, Maharashtra, India (IEC number: IEC/Sept-2019/8367).

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Conflicts of interest

The authors declare that there are no conflicts of interests.

Data and materials availability

All data associated with this study are present in the paper.

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